

- 1     1.     A composite osteoimplant, comprising:  
2           a polymer; and  
3           bone-derived particles, wherein  
4           the composite is adapted and constructed to be formable during implantation or  
5           immediately prior to implantation and to be set under predetermined  
6           conditions.
- 7     2.     The osteoimplant of claim 1, wherein the composite is formable at room  
8           temperature.
- 9     3.     The osteoimplant of claim 1, wherein the composite is not formable at about  
10          37°C, and wherein the composite becomes formable when heated to a temperature  
11          greater than about 40°C.
- 12    4.     The osteoimplant of claim 3, wherein the composite becomes formable when  
13          heated to a temperature greater than about 45°C.
- 14    5.     The osteoimplant of claim 4, wherein the composite becomes formable when  
15          heated to a temperature greater than about 50°C.
- 16    6.     The osteoimplant of claim 5, wherein the composite becomes formable when  
17          heated to a temperature greater than about 55°C.
- 18    7.     The osteoimplant of claim 6, wherein the composite becomes formable when  
19          heated to a temperature greater than about 60°C.
- 20    8.     The osteoimplant of claim 7, wherein the composite becomes formable when  
21          heated to a temperature greater than about 70°C.
- 22    9.     The osteoimplant of claim 8, wherein the composite becomes formable when  
23          heated to a temperature greater than about 80°C.

- 1 10. The osteoimplant of claim 9, wherein the composite becomes formable when  
2 heated to a temperature greater than about 90°C.
- 3 11. The osteoimplant of claim 1, wherein the composite is set by increasing the cross-  
4 link density of the polymer component.
- 5 12. The osteoimplant of claim 1, wherein the composite further comprises a  
6 monomer, the composite becoming set when the monomer is covalently  
7 incorporated into the polymer.
- 8 13. The osteoimplant of claim 1, wherein the composite further comprises at least one  
9 member of bone marrow, a biomolecule, a small molecule, a bioactive agent,  
10 calcium phosphate, calcium carbonate, and cells.
- 11 14. The osteoimplant of claim 13, wherein the composite further comprises at least  
12 one member of a nucleic acid vector, mesenchymal stem cells, osteoblasts,  
13 osteoclasts, and fibroblasts.
- 14 15. The osteoimplant of claim 14, wherein the nucleic acid vector, when introduced  
15 into a cell, increases the cell's production of bone morphogenetic proteins.
- 16 16. The osteoimplant of claim 1, wherein the osteoimplant is adapted and constructed  
17 to be irrigated following implantation without substantially changing its shape.
- 18 17. The osteoimplant of claim 1, wherein the bone-derived particles are selected from  
19 the group consisting of nondemineralized bone particles, partially demineralized  
20 bone particles, superficially demineralized bone particles, fully demineralized  
21 bone particles and mixtures thereof.
- 22 18. The osteoimplant of claim 1, wherein the bone-derived particles are obtained from  
23 a member of the group consisting of cortical bone, cancellous bone, cortico-  
24 cancellous bone, and mixtures thereof.

- 1 19. The osteoimplant of claim 1, wherein the bone-derived particles are obtained from  
2 a member of the group consisting of autogenous bone, allogenic bone, xenogeneic  
3 bone, transgenic bone, and mixtures thereof.
- 4 20. The osteoimplant of claim 1, wherein the bone-derived particles are about 10% to  
5 about 99% by weight of the composite.
- 6 21. The osteoimplant of claim 20, wherein the bone-derived particles are about 25%  
7 to about 50% by weight of the composite.
- 8 22. The osteoimplant of claim 1, wherein a surface of the bone-derived particles is  
9 modified with a member of a biomolecule, a small molecule, a bioactive agent, a  
10 non-biologically active material, and any combination of the above.
- 11 23. The osteoimplant of claim 22, wherein the member is linked to the surface by a  
12 coupling agent.
- 13 24. The osteoimplant of claim 1, wherein at least a portion of the bone-derived  
14 particles are covalently linked to one another.
- 15 25. The osteoimplant of claim 1, wherein collagen fibers at the surface of the bone-  
16 derived particles are exposed.
- 17 26. The osteoimplant of claim 25, wherein the exposed collagen fibers are partially or  
18 fully separated from one another.
- 19 27. The osteoimplant of claim 25, wherein the exposed collagen fibers are derivatized  
20 with a moiety selected from the group consisting of a biomolecule, a small  
21 molecule, a bioactive agent, a non-biologically active material, and any  
22 combination of the above.
- 23 28. The osteoimplant of claim 1, wherein the polymer is selected from the group  
24 consisting of biodegradable polymers, non-biodegradable polymers, co-polymers

- 1 of biodegradable polymers, co-polymers of non-biodegradable polymers, and co-  
2 polymers of biodegradable and non-biodegradable polymers, and mixtures of any  
3 of the above.
- 4 29. The osteoimplant of claim 25, wherein the polymer is selected from the group  
5 consisting of starch poly(caprolactone), poly(caprolactone), poly(l-lactide),  
6 poly(dl-lactide-co-glycolide), poly(l-lactide-co-dl-lactide), enantiomers of the  
7 above, co-polymers of the above, and mixtures of the above.
- 8 30. The osteoimplant of claim 1, wherein the polymer is selected from the group  
9 consisting of poly(arylates), poly(anhydrides), poly(hydroxy acids), polyesters,  
10 poly(ortho esters), polycarbonates, poly(propylene fumerates), poly(amide esters),  
11 poly(amide carbonates), poly(caprolactones), polyamides, polyamino acids,  
12 polyacetals, polylactides, polyglycolides, poly(dioxanones), polyhydroxybutyrate,  
13 polyhydroxyvalyrate, poly(vinyl pyrrolidone), biodegradable polycyanoacrylates,  
14 biodegradable polyurethanes, polysaccharides, tyrosine-based polymers,  
15 polyalkylene oxides, polymino carbonates, polyester amides, polyester imides,  
16 amino acid polyarylates, amino acid polycarbonates, poly(pyrrole), poly(aniline),  
17 poly(thiophene), polystyrene, non-biodegradable polyurethanes, polyureas,  
18 poly(ethylene vinyl acetate), polypropylene, polymethacrylate, polyethylene,  
19 poly(ethylene oxide), co-polymers of the above, adducts of the above, and  
20 mixtures of any of the above.
- 21 31. The osteoimplant of claim 1, wherein the bone derived particles and the polymer  
22 are linked with a coupling agent.
- 23 32. The osteoimplant of claim 1, wherein the osteoimplant has a shape selected from  
24 the group consisting of a bone, a section of a bone, sheet, plate, particle, sphere,  
25 hemisphere strand, coiled strand, capillary network, film, fiber, mesh, disk, cone,  
26 portion of a cone, pin, screw, tube, cup, tooth, tooth root, strut, wedge, portion of

- 1 wedge, cylinder, threaded cylinder, rod, hinge, rivet, anchor, spheroid, ellipsoid,  
2 oblate spheroid, prolate ellipsoid, or hyperbolic paraboloid.
- 3 33. The osteoimplant of claim 1, wherein the osteoimplant comprises a plurality of  
4 pieces of composite, wherein the pieces are joined together.
- 5 34. The osteoimplant of claim 33, wherein the pieces are joined together with a  
6 member of an adhesive, a mechanical fastener, ultrasonic bonding, and any  
7 combination of the above.
- 8 35. The osteoimplant of claim 1, wherein the composite is adapted and constructed to  
9 be formed in a mold.
- 10 36. The osteoimplant of claim 1, wherein the distribution of bone-derived particles  
11 within the composite is not uniform with respect to a member of volume fraction,  
12 size, density, shape, size distribution, and any combination of the above.
- 13 37. The osteoimplant of claim 1, wherein at least a portion of the bone-derived  
14 particles in the composite are elongate, and wherein an arrangement of bone-  
15 derived particles in the composite is isotropic or anisotropic.
- 16 38. The osteoimplant of claim 1, wherein at least a portion of the bone-derived  
17 particles in the composite are elongate, and wherein a relative alignment of bone-  
18 derived particles in a first portion of the composite is different than the relative  
19 alignment of bone-derived particles in a second portion of the composite.
- 20 39. A method of preparing an osteoimplant, comprising:  
21 forming a composite comprising bone-derived particles and a polymer into a  
22 predetermined shape; and  
23 causing the polymer to set.
- 24 40. The method of claim 39, further comprising combining the composite with  
25 autogenous tissue.

- 1 41. The method of claim 39, wherein the predetermined shape is that of a wound site  
2 in a bone and the step of forming comprises packing the wound site with the  
3 composite.
- 4 42. The method of claim 39, further comprising, before the step of forming, heating  
5 the composite to a temperature at which it is more formable.
- 6 43. The method of claim 42, wherein the step of causing comprises allowing the  
7 composite to cool to ambient temperature.
- 8 44. The method of claim 43, wherein the step of causing comprises allowing the  
9 composite to cool to body temperature.
- 10 45. The method of claim 39, wherein the step of causing comprises increasing the  
11 cross-link density of the polymer.
- 12 46. The method of claim 39, further comprising adding a mechanical fastener to the  
13 osteoimplant, wherein the step of forming comprises forming the composite to  
14 retain the mechanical fastener after the step of causing.
- 15 47. The method of claim 39, wherein the bone particles are about 10% to about 99%  
16 by weight of the composite.
- 17 48. The method of claim 39, wherein the composite further comprises at least one  
18 member of bone marrow, a biomolecule, a small molecule, a bioactive molecule,  
19 calcium phosphate, calcium carbonate, and cells.
- 20 49. The method of claim 48, wherein the composite further comprises a member of a  
21 nucleic acid vector, mesenchymal stem cells, osteoblasts, osteoclasts, and  
22 fibroblasts.
- 23 50. The method of claim 49, wherein the nucleic acid vector, when introduced into a  
24 cell, increases the cell's production of bone morphogenetic proteins.

- 1 51. The method of claim 39, wherein the polymer is selected from the group  
2 consisting of biodegradable, non-biodegradable, co-polymers of biodegradable  
3 polymers, co-polymers of non-biodegradable polymers, and co-polymers of  
4 biodegradable and non-biodegradable polymers.
- 5 52. The method of claim 51, wherein the polymer is selected from the group  
6 consisting of starch poly(caprolactone), poly(caprolactone), poly(l-lactide),  
7 poly(dl-lactide-co-glycolide), poly(l-lactide-co-dl-lactide), enantiomers of the  
8 above, co-polymers of the above, and mixtures of the above.
- 9 53. The method of claim 39, wherein the bone derived particles and the polymer are  
10 linked with a coupling agent.
- 11 54. The method of claim 39, wherein the predetermined shape is selected from the  
12 group consisting of a bone, a section of a bone, sheet, plate, particle, sphere,  
13 hemisphere strand, coiled strand, capillary network, film, fiber, mesh, disk, cone,  
14 portion of a cone, pin, screw, tube, cup, tooth, tooth root, strut, wedge, portion of  
15 wedge, cylinder, threaded cylinder, rod, hinge, rivet, anchor, spheroid, ellipsoid,  
16 oblate spheroid, prolate ellipsoid, or hyperbolic paraboloid.
- 17 55. The method of claim 39, further comprising forming at least a second composite,  
18 causing the polymer in the second composite to set, and joining the composites  
19 together to form an osteoimplant.
- 20 56. The method of claim 39, further comprising machining the composite into a  
21 shape, wherein the step of machining is performed before the step of forming,  
22 after the step of forming, before the step of causing, after the step of causing, or  
23 any combination of the above.
- 24 57. The method of claim 39, further comprising combining bone-derived particles and  
25 a polymer to form the composite.

- 1 58. The method of claim 57, wherein the step of combining comprises a member of  
2 pressing a mixture of polymer and bone-derived particles, hand mixing bone-  
3 derived particles into formable polymer, heating the polymer, solvent casting a  
4 polymer and bone-derived particles, injection molding, extrusion forming,  
5 pressing a coating of bone-derived particles into a sheet of polymer, and  
6 combining the polymer with a solvent.
- 7 59. The method of claim 39, wherein the step of forming comprises a member of  
8 shaping the composite in a mold and arranging the composite in a tissue site.
- 9 60. The method of claim 39, wherein at least a portion of the bone-derived particles in  
10 the composite are elongate, and wherein an arrangement of bone-derived particles  
11 in the composite is isotropic or anisotropic.
- 12 61. The method of claim 39, wherein at least a portion of the bone-derived particles in  
13 the composite are elongate, and wherein a relative alignment of bone-derived  
14 particles in a first portion of the composite is different than the relative alignment  
15 of bone particles in a second portion of the composite.
- 16 62. The method of claim 39, wherein at least a portion of the bone-derived particles  
17 are covalently linked to one another.
- 18 63. A kit for producing an osteoimplant, comprising:  
19 a polymer adapted and constructed to be formable under a first predetermined  
20 condition and set under a second predetermined condition; and  
21 bone-derived particles,  
22 wherein, under the first predetermined condition, the polymer and the bone-  
23 derived particles may be combined and formed into a predetermined  
24 shape.
- 25 64. The kit of claim 63, wherein the predetermined conditions are a temperature  
26 greater than about 40°C.



- 1 65. The kit of claim 63, wherein the polymer is set by exposing it to an energy source  
2 for a predetermined period of time.
- 3 66. The kit of claim 63, wherein the osteoimplant is adapted and constructed to be  
4 irrigated following implantation without substantially changing its shape.
- 5 67. The kit of claim 63, wherein the bone particles are about 10% to about 99% by  
6 weight of the composite.
- 7 68. The kit of claim 63, wherein the composite further comprises at least one member  
8 of bone marrow, a biomolecule, a small molecule, a bioactive molecule, calcium  
9 phosphate, calcium carbonate, and cells.
- 10 69. The kit of claim 63, wherein the composite further comprises a member of a  
11 nucleic acid vector, mesenchymal stem cells, osteoblasts, osteoclasts, and  
12 fibroblasts.
- 13 70. The kit of claim 68, wherein the nucleic acid vector, when introduced into a cell,  
14 increases the cell's production of bone morphogenetic proteins.
- 15 71. The kit of claim 63, wherein the polymer is selected from the group consisting of  
16 biodegradable, non-biodegradable, co-polymers of biodegradable polymers, co-  
17 polymers of non-biodegradable polymers, and co-polymers of biodegradable and  
18 non-biodegradable polymers.
- 19 72. The kit of claim 68, wherein the polymer is selected from the group consisting of  
20 starch poly(caprolactone), poly(caprolactone), poly(l-lactide), poly(dl-lactide-co-  
21 glycolide), poly(l-lactide-co-dl-lactide), enantiomers of the above, co-polymers of  
22 the above, and mixtures of the above.
- 23 73. The kit of claim 63, wherein the bone derived particles and the polymer are linked  
24 with a coupling agent.

- 1 74. The kit of claim 63, wherein the osteoimplant has a shape selected from the group  
2 consisting of a bone, a section of a bone, sheet, plate, particle, sphere, hemisphere  
3 strand, coiled strand, capillary network, film, fiber, mesh, disk, cone, portion of a  
4 cone, pin, screw, tube, cup, tooth, tooth root, strut, wedge, portion of wedge,  
5 cylinder, threaded cylinder, rod, hinge, rivet, anchor, spheroid, ellipsoid, oblate  
6 spheroid, prolate ellipsoid, or hyperbolic paraboloid.
- 7 75. The kit of claim 63, wherein the predetermined shape is defined by a mold.
- 8 76. The kit of claim 63, wherein the composite is adapted and constructed to be  
9 implanted by forming it within a tissue site.
- 10 77. A method of producing a composite for use in an osteoimplant, comprising:  
11 providing a polymer adapted and constructed to be formable under a first  
12 predetermined condition and set under a second predetermined condition;  
13 providing a plurality of bone-derived particles; and  
14 combining the polymer and the plurality of bone-derived particles under the first  
15 predetermined condition.
- 16 78. The method of claim 77, wherein the step of combining comprises combining the  
17 polymer and the plurality of bone-derived particles with autogenous tissue.
- 18 79. The method of claim 77, further comprising, before the step of combining,  
19 heating the polymer to a temperature at which it is formable.
- 20 80. The method of claim 79, wherein the temperature is greater than about 40°C.
- 21 81. The method of claim 80, wherein the temperature is greater than about 45°C.
- 22 82. The method of claim 81, wherein the temperature is greater than about 50°C.
- 23 83. The method of claim 82, wherein the temperature is greater than about 55°C.

- 1     84.     The method of claim 83, wherein the temperature is greater than about 60°C.
- 2     85.     The method of claim 84, wherein the temperature is greater than about 70°C.
- 3     86.     The method of claim 85, wherein the temperature is greater than about 80°C.
- 4     87.     The method of claim 86, wherein the temperature is greater than about 90°C.
- 5     88.     The method of claim 79, further comprising, after the step of combining, allowing  
6            the composite to cool to ambient temperature.
- 7     89.     The method of claim 79, further comprising, after the step of combining, allowing  
8            the composite to cool to body temperature.
- 9     90.     The method of claim 77, further comprising incorporating a mechanical fastener  
10           into the composite.
- 11    91.     The method of claim 77, wherein the bone-derived particles are selected from the  
12           group consisting of nondemineralized bone particles, partially demineralized bone  
13           particles, superficially demineralized bone particles, fully demineralized bone  
14           particles and mixtures thereof.
- 15    92.     The method of claim 77, wherein the bone-derived particles are obtained from a  
16           member of the group consisting of cortical bone, cancellous bone, cortico-  
17           cancellous bone, and mixtures thereof.
- 18    93.     The method of claim 77, wherein the bone-derived particles are obtained from a  
19           member of the group consisting of autogenous bone, allogenic bone, xenogeneic  
20           bone, transgenic bone, and mixtures thereof.
- 21    94.     The method of claim 77, wherein the bone-derived particles are about 10% to  
22           about 99% by weight of the composite.

- 1 95. The method of claim 94, wherein the bone-derived particles are about 25% to  
2 about 50% by weight of the composite.
- 3 96. The method of claim 77, further comprising modifying a surface of the bone-  
4 derived particles with a member of a biomolecule, a small molecule, a bioactive  
5 agent, a non-biologically active material, and any combination of the above.
- 6 97. The method of claim 77, further comprising linking a member of a biomolecule, a  
7 small molecule, a bioactive agent, a non-biologically active material, and any  
8 combination of the above to a surface of the bone-derived particles with a  
9 coupling agent.
- 10 98. The method of claim 77, further comprising covalently linking at least a portion  
11 of the bone-derived particles to one another.
- 12 99. The method of claim 77, wherein the step of combining comprises combining the  
13 bone-derived particles and polymer with at least one member of bone marrow, a  
14 biomolecule, a small molecule, a bioactive molecule, calcium phosphate, calcium  
15 carbonate, and cells.
- 16 100. The method of claim 98, wherein the step of combining comprises combining the  
17 bone-derived particles and polymer with at least one member of a nucleic acid  
18 vector, mesenchymal stem cells, osteoblasts, osteoclasts, and fibroblasts.
- 19 101. The method of claim 100, wherein the nucleic acid vector, when introduced into a  
20 cell, increases the cell's production of bone morphogenetic proteins.
- 21 102. The method of claim 77, further comprising exposing collagen fibers at the  
22 surface of the bone particles.
- 23 103. The method of claim 102, further comprising partially or fully separating the ends  
24 of exposed collagen fibers from one another.

- 1    104.    The method of claim 102, further comprising derivatizing the exposed collagen  
2            fibers with a moiety selected from the group consisting of a biomolecule, a small  
3            molecule, a bioactive agent, a non-biologically active material, and any  
4            combination of the above.
- 5    105.    The method of claim 77, wherein the polymer is selected from the group  
6            consisting of biodegradable, non-biodegradable, co-polymers of biodegradable  
7            polymers, co-polymers of non-biodegradable polymers, and co-polymers of  
8            biodegradable and non-biodegradable polymers.
- 9    106.    The method of claim 105, wherein the polymer is selected from the group  
10           consisting of starch poly(caprolactone), poly(caprolactone), poly(l-lactide),  
11           poly(dl-lactide-co-glycolide), poly(l-lactide-co-dl-lactide), enantiomers of the  
12           above, co-polymers of the above, and mixtures of the above.
- 13   107.    The method of claim 105, wherein the polymer is selected from the group  
14           consisting of poly(arylates), poly(anhydrides), poly(hydroxy acids), polyesters,  
15           poly(ortho esters), polycarbonates, poly(propylene fumerates), poly(amide esters),  
16           poly(amide carbonates), poly(caprolactones), polyamides, polyamino acids,  
17           polyacetals, polylactides, polyglycolides, poly(dioxanones), polyhydroxybutyrate,  
18           polyhydroxyvalyrate, poly(vinyl pyrrolidone), biodegradable polycyanoacrylates,  
19           biodegradable polyurethanes, polysaccharides, tyrosine-based polymers,  
20           polyalkylene oxides, polymino carbonates, polyester amides, polyester imides,  
21           amino acid polyarylates, amino acid polycarbonates, poly(pyrrole), poly(aniline),  
22           poly(thiophene), polystyrene, non-biodegradable polyurethanes, polyureas,  
23           poly(ethylene vinyl acetate), polypropylene, polymethacrylate, polyethylene,  
24           poly(ethylene oxide), co-polymers of the above, adducts of the above, and  
25           mixtures of any of the above.
- 26   108.    The method of claim 77, wherein the bone derived particles and the polymer are  
27           linked with a coupling agent.

- 1 109. The method of claim 77, wherein the composite is adapted and constructed to be  
2 formable into a shape selected from the group consisting of a bone, a section of a  
3 bone, sheet, plate, particle, sphere, hemisphere strand, coiled strand, capillary  
4 network, film, fiber, mesh, disk, cone, portion of a cone, pin, screw, tube, cup,  
5 tooth, tooth root, strut, wedge, portion of wedge, cylinder, threaded cylinder, rod,  
6 hinge, rivet, anchor, spheroid, ellipsoid, oblate spheroid, prolate ellipsoid, or  
7 hyperbolic paraboloid.
- 8 110. The method of claim 77, wherein the composite is adapted and constructed to be  
9 formable into a shape of a wound site in a bone.
- 10 111. The method of claim 77, wherein the composite is adapted and constructed to be  
11 shaped in a mold.
- 12 112. The method of claim 77, further comprising producing at least a second  
13 composite and joining the composites together to form an osteoimplant.
- 14 113. The method of claim 112, wherein the composites are joined together with a  
15 member of an adhesive, a mechanical fastener, ultrasonic bonding, and any  
16 combination of the above.
- 17 114. The method of claim 77, further comprising machining the composite into a  
18 shape.
- 19 115. The method of claim 77, wherein the step of combining comprises a member of  
20 pressing a mixture of polymer and bone-derived particles, hand mixing bone-  
21 derived particles into formable polymer, heating the polymer, solvent casting a  
22 polymer and bone-derived particles, injection molding, extrusion forming,  
23 pressing a coating of bone-derived particles into a sheet of polymer, and  
24 combining the polymer with a solvent.

- 1 116. The method of claim 77, wherein the composite is adapted and constructed to be  
2 formed into a shape in a member of a mold and a tissue site under the  
3 predetermined conditions.
- 4 117. The method of claim 77, wherein the composite becomes set because the cross-  
5 link density of the polymer is increased.
- 6 118. The method of claim 77, wherein the step of combining comprises combining a  
7 monomer with the plurality of bone-derived particles and the polymer, and when  
8 the composite becomes set when the monomer is incorporated into the polymer.
- 9 119. The method of claim 77, wherein the composite becomes set when the polymer is  
10 brought to a temperature less than a temperature at which the polymer is  
11 formable.
- 12 120. The method of claim 77, wherein at least a portion of the bone particles in the  
13 composite are elongate, and wherein an arrangement of bone-derived particles in  
14 the composite is isotropic or anisotropic.
- 15 121. The method of claim 77, wherein at least a portion of the bone-derived particles in  
16 the composite are elongate, and wherein a relative alignment of bone-derived  
17 particles in a first portion of the composite is different than the relative alignment  
18 of bone-derived particles in a second portion of the composite.